Paper No. 42

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JAMES E. DARNELL JR.,
CHRISTIAN W. SCHINDLER,
XIN-YUAN FU,
ZILONG WEN, and
ZHONG ZHONG

Appeal No. 2001-0121
Application No. 08/212,185

ON BRIEF

Before WINTERS, SCHEINER, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 96-103, which are all the claims pending in the application.

Claims 100 and 103 are illustrative of the subject matter on appeal and are reproduced below:

> 100. A method of identifying a potential drug having the ability to modulate the binding of an activated receptor recognition factor to a DNA ligand in vitro comprising:
>
> (a) contacting a small molecule with a purified activated receptor recognition factor; wherein in the absence of the small molecule the purified activated receptor recognition factor is able to bind to the DNA ligand in vitro;

(b) determining the amount of binding between the purified activated receptor recognition factor and the DNA ligand in the presence of the small molecule; and

(c) comparing the amount of binding in step (b) with the amount of binding determined in the absence of the small molecule; wherein the small molecule is identified as a potential drug having the ability to modulate the binding of the activated receptor recognition factor to the DNA ligand in vitro when said comparing indicates a change in the amount of binding of the activated receptor recognition factor to the DNA ligand.

103. A method of detecting a phosphorylated receptor recognition factor comprising:

(a) contacting the phosphorylated receptor recognition factor with a labeled-antibody specific for the phosphorylated receptor recognition factor under conditions in which the labeled-antibody binds to the phosphorylated receptor recognition factor; and

(b) detecting the labeled-antibody bound to the phosphrylated receptor recognition factor, wherein said detecting allows the detection of the phosphorylated receptor recognition factor.

The references relied upon by the examiner are:

Fu et al. (Fu), "ISGF3, the transcriptional activator induced by interferon α, consists of multiple interacting polypeptide chains," Proc. Natl. Acad. Sci. USA, Vol. 87, pp. 8555-8559 (1990)

Decker et al. (Decker), "Two distinct Alpha-Interferon-Dependent signal transduction pathways may contribute to activation of transcription of the guanylate-binding protein gene," Mol. Cell. Bio., Vol. 11, No. 10, pp. 5147-5153 (1991)

The reference relied upon by appellants is:

Darnell, Molecular Cell Biology Fig. 6-2 legend (J. Darnell et al. eds., 2nd ed., 1990)

GROUNDS OF REJECTION

Claims 96-103 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the full scope of the claimed invention.

Claim 100 stands rejected under 35 U.S.C. § 102(a) as anticipated by Decker.

Claims 97-102 stand rejected under 35 U.S.C. § 103 as being unpatentable over Fu.

For the reasons that follow, we reverse the rejections under 35 U.S.C. § 112, first paragraph and § 103. We vacate the rejection under 35 U.S.C. § 102(a) and remand the application to the examiner to consider the following issues and to take appropriate action

DISCUSSION

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

According to the examiner (Answer, page 3), "the specification, while being enabling for detection of receptor recognition factors having molecular weights of 113 kD, 91 kD or 84 kD, as described in the specification, does not reasonably provide enablement for the scope of the claims, which encompass detection of any and all possible 'receptor recognition factor(s)'."

In support of her position, the examiner makes the following observations (Answer, page 4), the claimed methods:

> require[] that the person of ordinary skill in the art have knowledge of (1) the protein being detected such that the protein can be distinguished from all other proteins, (2) the identity of the DNA

> sequence to which the protein binds, as well as (3) possession of antibodies specific to the protein in its phosphorylated state.

With regard to the first observation, the examiner finds (id.), "the claims are not limited to the detection of any particular protein…." Therefore, the examiner concludes (Answer, bridging sentence, pages 4-5), "[i]t would require undue experimentation to isolate other receptor recognition factors, determine their DNA ligands and the identity of the receptors which they recognize and develop appropriate detection methods to allow practice of the claimed invention in a manner commensurate in scope with the claims."

With regard to the second observation, the examiner finds (Answer, page 4), "[i]t would require undue experimentation to determine the DNA ligand of the 84 kD protein as required to practice claims 99 and 100." Therefore, the examiner concludes (id.), "[i]n the absence of any guidance as to the chemical structure of that DNA ligand, it is unpredictable that the person of ordinary skill in the art could practice the invention of claims 99 and 100 as they relate to the 84 kD protein without undue experimentation."

With regard to the third observation, the examiner finds (Answer, page 5), that while the specification makes use of anti-phosphotyrosine antibodies, "there is no disclosure in the specification as filed of antibodies which are specific for a phosphorylated receptor recognition factor." According to the examiner (id.):

> It would require undue experimentation to determine how to get a sufficient quantity of the desired protein in its phosphorylated and non-phosphorylated forms, generate antibodies to the phosphorylated form, and then eliminate the possibility that the antibodies obtained are not specific to the phosphorylated form of the particular protein, as opposed to either the non-phosphorylated

> form or the phosphotyrisone itself (as anti-phosphotyrosine antibodies are well known in the art).

On reflection, it is our opinion that the examiner failed to provide the evidence necessary to meet her burden of establishing a prima facie case of non-enablement. Instead, we agree with appellants argument (Brief, bridging sentence, pages 12-13) that "[a]ppellants are not required to teach how to isolate and characterize all of the receptor recognition factors that the method can be performed on …, but rather are only required to enable the claimed methodology such that it can be used on any given receptor recognition factor."

The enablement requirement of 35 U.S.C. § 112, first paragraph, requires that the patent specification enable "those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation.'" Genentech, Inc. v. Novo Nordisk. A/S, 108 F.3d at 1365, 42 USPQ2d at 1004 (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether the disclosure is enabling, is a legal conclusion based on several underlying factual inquiries. To assist the fact finder in meeting his initial burden of setting forth a reasonable explanation as to why he believes the scope of the claimed invention is not adequately enabled by the description, our appellate reviewing court has outlined a number of factors that should be considered. As set forth in In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988), the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature

of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

We find no analysis of the Wands factors by the examiner. Instead, we find only the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. We remind the examiner that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. In re Marzocchi, 439 F.2d at 223, 169 USPQ at 369. In the absence of a fact-based statement of a rejection based upon the relevant legal standards, the examiner has not sustained her initial burden of establishing a prima facie case of non-enablement. The burden of proof does not shift to appellant until the examiner first meets her burden. Id., 439 F.2d at 223-224, 169 USPQ at 369-370. We recommend that the examiner review Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999), wherein our appellate reviewing court provided a model analysis of enablement issues and illustrated the type of fact finding which is needed before one is in a proper position to determine whether a given claim is enabled or non-enabled.

For the reasons set forth above, we are compelled to reverse the rejection of claim 96-103 under 35 U.S.C. § 112, first paragraph.

THE REJECTION UNDER 35 U.S.C. § 102:

According to the examiner (Answer, page 6), Decker "disclose assays in which binding of activated RRFs to DNA added to cellular extracts was

measured … [and] [a]t page 5149 they disclose adding a series of mutated promoter fragments ('small molecules') to determine the effect on the binding."

In our opinion, the examiner's position is inconsistent with her withdrawal of the rejection of claims 99 and 100 under 35 U.S.C. § 112, second paragraph. See Answer, page 2. According to the examiner's Final Rejection (Paper No.28, page 3),

> Claims 99 and 100 remain indefinite because the metes and bounds of "small molecules" cannot be determined. Applicants argument that "the skilled artisan would appreciate the metes and bounds of the term []small molecule" has been fully considered but is not deemed persuasive. Applicants have failed to point to any fact or evidence that such has a clearly defined meaning in the art.

The examiner, however, withdrew this rejection; apparently[1], in response to appellants' reliance (Brief, page 8) on Darnell to demonstrate that "the skilled artisan would appreciate the metes and bounds of the term 'small molecule' which is commonly used in the relevant field of drug design and screening." According to appellants (id.), in Darnell:

> the term "small soluble molecule" is described as follows…:
>
> > A cell's pool of small soluble molecules- amino acids (aa) and nucleotides (dNTP and rNTP)- may be separated from the macromolecules (DNA, RNA, and proteins) by adding cold acid, usually trichloracetic acid (TCA), which destroys the cell structure and precipitates all macromolecules….

In responding to the examiner's rejection of claim 100 under 35 U.S.C. § 102(a) over Decker, appellants (relying again on Darnell and their arguments with regard to the examiner's rejection under 35 U.S.C. § 112, second

[1] The examiner offers no explanation as to why she withdrew the rejection under 35 U.S.C. § 112, second paragraph.

paragraph) point out (Brief, page 15), "as already indicated … the mutated promoters employed by Decker et al. are not small molecules."

The examiner, however, finds (Answer, page 15), the term "small molecules" is a relative term of which there is no definition in the specification. Accordingly, the examiner argues (Answer, bridging sentence pages 15-16), "in the absence of any express definition, or any single generally accepted definition in the art, … [Decker's] promoter fragments are within the broadest reasonable interpretation of the term 'small molecules' [emphasis added]."

In our opinion, the inconsistent treatment of the term "small molecule" with regard to the rejections under 35 U.S.C. § 112, second paragraph, and § 102(a) has introduced substantial confusion into this record with regard to the scope of the claim. In this regard, we remind the examiner that analyzing claims based on "speculation as to meaning of the terms employed and assumptions as to the scope of such claims" is legal error. In re Steele, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962).

Accordingly, we vacate[2] the rejection of claim 100 under 35 U.S.C. § 102(a), and remand the application to the examiner for further consideration.

[2] Lest there be any misunderstanding, the term "vacate" in this context means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists. Cf. Ex parte Zambrano, 58 USPQ2d 1312, 1313 (Bd. Pat. App. & Int. 2001).

Upon return of the application, the examiner should take a step back and reevaluate the claimed invention, together with the prior art, the disclosure of the invention found in appellant's specification and the prosecution history. Thereafter, if the examiner finds that a rejection is necessary, the examiner should issue an appropriate Office action setting forth such a rejection, using the proper legal standards and clearly setting for the facts relied upon in support of such a rejection. In this regard, we remind the examiner as set forth in In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989):

> [D]uring patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. . . . An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.

THE REJECTION UNDER 35 U.S.C. § 103:

According to the examiner (Answer, page 7), "[t]he disclosure of Fu differs from the rejected claims in that no potential drug was added in the assays." Nevertheless, the examiner asserts (id.) that it "would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the assays disclosed by Fu et al. to include the introduction of other substances, meeting the limitation of the claims of 'adding a potential drug'."

In addition, the examiner argues (Answer, page 16) that appellants have "not challenged or otherwise traversed" the examiner's Official Notice, "that it would have been obvious to modify the assays as disclosed by Fu et al. to include the introduction of other substances, including small molecules…." We

do not agree with the examiner's position that appellants have not challenged or otherwise traversed the examiner's position. As set forth in appellants' (Brief, page 16), "[t]he lone reference cited by the Examiner, Fu et al., does not contain the teachings required to construct the methods as claimed. … The examiner cannot cure these deficiencies solely by taking Official Notice." Similarly, appellants argue (Reply Brief, page 8), "the Examiner cannot establish the requisite motivation and expectation of success to meet her burden for making a prima facie case of obviousness by simply taking Official Notice, when the prior art cited lacks both a critical component of the claim and the step of using that component."

Furthermore, we agree with appellants' argument that the examiner has improperly utilized the concept of Official Notice to supply a critical limitation of appellants' claimed invention that is missing in the prior art relied upon by the examiner. As set forth in In re Ahlert and Kruger, 424 F.2d 1088, 1091, 165 USPQ 418, 420-21 (CCPA 1970) (Emphasis added):

> the Patent Office … may take notice of facts beyond the record which, while not generally notorious, are capable of such instant and unquestionable demonstration as to defy dispute. In re Knapp Monarch Co., 49 CCPA 779, 296 F.2d 230, 132 USPQ 6 (1961). This rule is not, however, as broad as it first might appear, and this court will always construe it narrowly and will regard facts found in such manner with an eye toward narrowing the scope of any conclusions to be drawn therefrom. Assertions of technical facts in areas of esoteric technology must always be supported by citation to some reference work recognized as standard in the pertinent art and the appellant given, in the Patent Office, the opportunity to challenge the correctness of the assertion or the notoriety or repute of the cited reference. Cf. In re Cofer, 53 CCPA 830, 354 F.2d 664, 148 USPQ 268 (1966), In re Borst, 52 CCPA 1398, 345 F.2d 851, 145 USPQ 554 (1965). Allegations concerning specific "knowledge" of the prior art, which might be

> peculiar to a particular art should also be supported and the appellant similarly given the opportunity to make a challenge. See In re Spormann, 53 CCPA 1375, 363 F.2d 444, 150 USPQ 449 (1966). …
>
> Typically, it is found necessary to take notice of facts which may be used to supplement or clarify the teaching of a reference disclosure, perhaps to justify or explain a particular inference to be drawn from the reference teaching. The facts so noticed serve to "fill in the gaps" which might exist in the evidentiary showing made by the examiner to support a particular ground for rejection. We know of no case in which facts judicially noticed comprised the principal evidence upon which a rejection was based….

While a person of ordinary skill in the art may possess the requisite knowledge and ability to modify the protocol taught by Fu, the modification is not obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 211 USPQ 1125, 1127 (Fed. Cir. 1984). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there are some teachings, suggestions, or motivations to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

On this record there is no suggestion in the prior art to modify Fu in a manner to obtain appellants' claimed invention. Instead, the only suggestion to modify Fu comes from the examiner's assertion that one of ordinary skill in the art at the time the invention was made would have found it obvious to modify Fu in a manner to obtain appellants' claimed invention. In this regard, we note as set forth in W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983):

> To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

Based on the evidence before us we are compelled to find that the examiner failed to meet her burden[3] of presenting the evidence to establish a prima facie case of obviousness. Accordingly, we reverse the rejection of claims 97-102 under 35 U.S.C. § 103 as being unpatentable over Fu.

SUMMARY

The rejection of claims 96-103 under 35 U.S.C. § 112, first paragraph, is reversed.

The rejection of claim 100 under 35 U.S.C. § 102(a) as anticipated by Decker is vacated.

The rejection of claims 97-102 under 35 U.S.C. § 103 as being unpatentable over Fu is reversed.

The application is remanded to the examiner, as discussed supra, for further consideration as to the scope of the term “small molecules” in the context of appellants’ claimed invention.

[3] In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

FUTURE PROCEEDINGS

We state that we are not authorizing a Supplemental Examiner's Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the examiner which contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

REVERSED-IN-PART, VACATED-IN-PART and REMANDED-IN-PART

Sherman D. Winters	)
Administrative Patent Judge	)
	)
	)
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Toni R. Scheiner	)
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